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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,713	04/04/2001	Matthew During	DUR01-NP001	3131

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	17

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/825,713	DURING ET AL.
	Examiner Konstantina Katcheves	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 March 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,8-13,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,8-13,16 and 17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim 1-4, 8-13, 16 and 17 are pending in the present application. This Office action is in response to Paper No. 16, filed 10 March 2003.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Response to Amendment

Claims 1-4, 8-13, 16 and 17 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods drawn to mice and rats, does not reasonably provide enablement for methods drawn to the treatment of human subjects for the reasons of record.

The rejection of claims 1-4, 8 and 9 under 35 U.S.C. 112, first paragraph has been withdrawn in view of Applicant's amendment and the declaration, filed on 10 March 2003.

Claims 1-4, 8 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Eglitis et al. (PNAS Vol.94 1997) for the reasons of record. The rejection of claims 8 and 9 under 35 U.S.C. 102(b) has been withdrawn in view of Applicant's arguments.

The rejections of claims 5-7, 14, 15, 18 and 19 are moot in view of the cancellation of these claims.

Response to Arguments

Claims 1-4, 8-13, 16 and 17 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods drawn to mice and rats, does not reasonably provide enablement for methods drawn to the treatment of human subjects for the reasons of record and those discussed below.

Applicant argues that the present claims are enabled for a method of modifying neuronal growth of all mammals wherein the neuronal and glial cells replace damaged nervous system cells. Applicant relies on an article, Mezey et al. as evidence of enablement for mammals other than rats and mice for the present methods. Applicant has provided a declaration by inventor, Matthew J. During, which discusses the Mezey et al. article as well.

According to MPEP 2164.01:

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) [emphasis added].

Applicant should note that the Mezey et al. reference relied upon as evidence of enablement of the invention for mammals other than mice and rats was published three years after the priority date of the present application. Thus, the disclosure of Mezey et al. is inappropriate evidence of the state of the art. Applicant's arguments and the declaration based on this reference fail to establish that Applicant was enabled for a method of targeted delivery of mammalian stem cells

of myeloid origin into the nervous system of any mammal wherein the stem cells migrate from the injection site and differentiate into neuronal or glial cells. As previously discussed, based on the specification and the state of the art, Applicant is enabled for the present method as it relates to rats and mice.

Claims 1-4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Eglitis et al. (PNAS Vol.94 1997) for the reasons of record.

Applicant has amended the claims to recite that the stem cells of myeloid origin differentiate into neuronal cells or neuronal and glial cells. Applicant argues that this limitation is not taught anywhere in Eglitis et al. Eglitis et al. discloses the transplantation of myeloid cells marked with a retroviral vector into the brains of mice. These cells are capable of migration to discrete parts of the brain and express the exogenous gene. Eglitis further discloses that myeloid derived cells acquire microglial antigenic markers and finds hematopoietically derived microglia in the brains of rats. See pages 4080 - 4081 and page 4082, column 1. Eglitis et al., however, discloses a method comprising the same method steps as claimed by Applicant. Given the close similarity of the method steps and the disclosure by Eglitis et al. that the myeloid cells differentiate into microglia, the differentiation of the myeloid stem cells to neuronal cells as well would be inherent. It is not necessary that the reference contemporaneously recognize such a characteristic where the similarity in the method steps disclosed by the reference and the method steps claimed indicate that the cells would inherently differentiate into neuronal cells as well.

See e.g. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999). Applicant also argues that Eglitis et al. fail to teach the selection of human myeloid

stem cells such as CD34⁺ cells. This limitation is not set forth in claims 1-4 which are drawn to myeloid cells generally.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 30, 2003

Remy Yucel
REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600